

Nevada State Immunization Program



Vaccines for Children Program (VFC) Protocol April 2015

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This document was created to help immunization providers follow all components of the Vaccines for Children (VFC) Program. If you have any additional questions or need clarification, then please call (775) 684-5900 or email nviz@health.nv.gov.

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Enrollment/Annual Re-Enrollment

The Vaccines for Children (VFC) Program is a federal entitlement program (CFDA #93.268) which allows immunization programs across the nation to purchase vaccines for VFC eligible children through the CDC contract. These vaccines are distributed, without charge, to provider sites that enroll in the VFC Program. Annually, each provider site must complete the forms listed below and return the completed forms to the Nevada State Immunization Program. **The provider should retain a copy of the completed enrollment form for three (3) years per CDC requirement, as well as for future reference.**

Re-Enrolling Providers Are Required To:

- Complete the “Vaccines for Children (VFC) Program Agreement to Participate” annually;
- Complete the Provider Profile Form annually, or if:
 - The number of children served changes, or
 - The status of the facility changes during the calendar year.
- Complete and have on site a “Vaccine Management Storage and Handling Plan.”
 - A template may be accessed at: http://health.nv.gov/Vaccine_VFCProgram.htm
 - If the template is not used by your office, then the plan you develop must contain all topics addressed in the template.

NEW Providers Are Required to:

- Complete the “Vaccines for Children (VFC) Program Agreement to Participate” initially and annually thereafter;
- Complete the Provider Profile Form (not necessary if brand new practice) initially and annually thereafter;
- Schedule an enrollment visit with state staff; and
- Complete and have on site a “Vaccine Management Storage and Handling Plan.”
 - A template may be accessed at: http://health.nv.gov/Vaccine_VFCProgram.htm
 - If the template is not used by your office, then the plan you develop must contain all topics addressed in the template.

NOTE: PRACTICES WITH MULTIPLE SITES MUST ENROLL EACH SITE AS A SEPARATE PROVIDER.

Requirements to Participate

By enrolling in the Nevada State Immunization Program, the provider agrees to:

To receive publicly funded vaccines at no cost, you the provider agree to the following conditions on behalf of yourself and all the practitioners, nurses, and others associated with the healthcare facility of which you are the medical director or equivalent:

1. Annually submit a provider profile representing the populations served by your practice/facility. You will need to submit the provider profile more frequently if 1) the number of children served changes or 2) the status of your facility changes during the calendar year.
2. Document vaccinations in records as required by the National Childhood Vaccine Injury Act (42 US Code 300aa-25). This law applies to all physicians that administer vaccines regardless of the age of the individual or the source of funding for the vaccine: www.law.cornell.edu/uscode/html/uscode42/usc_sec_42_00000300--aa025-.html
 - Date of administration of the vaccine;
 - Vaccine manufacturer and lot number;
 - Name and address, and if appropriate, the title of the health care provider administering the vaccine; and
 - Any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary of the Department of Health and Human Services.
 - In addition the following must be recorded:
 - Publication date of Vaccine Information Statement (VIS); and
 - Date VIS given to parent or legal guardian.
3. Maintain clients' immunization records for a period required by **NRS 629.051** and make such records available to the Nevada Department of Health and Human Services and/or the Federal Department of Health and Human Services. Make such records available to the health authority and/or designee, if requested (per NAC 441A.750). This includes collection of data for "Quality Improvement Assessments." www.leg.state.nv.us/Division/Legal/LawLibrary/NRS/NRS-629.html#NRS629Sec051
 - *#1: Each provider of health care shall retain the health care records of his or her patients as part of his or her regularly maintained records for 5 years after their receipt or production. Health care records may be retained in written form, or by microfilm or any other recognized form of size reduction, including, without limitation, microfiche, computer disc, magnetic tape, and optical disc... Health care records may be created, authenticated and stored in a computer system which limits access to those records.*
 - *#7. A provider of health care shall not destroy the health care records of a person who is less than 23 years of age on the date of the proposed destruction of the records. The health care records of a person who has attained the age of 23 years may be destroyed in accordance with this section for those records which have been retained for at least 5 years or for any longer period provided by federal law.*
4. Screen and document VFC eligibility for each child upon each visit prior to immunization; (see next section for details)
5. Adhere to the current Recommended Childhood Immunization Schedule as approved by the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP), American Academy of Family Physicians (AAFP), and the American College of Physicians (ACP); and
 - Comply with Nevada State Immunization Program guidelines including notices regarding ACIP recommendations, vaccine shortages, restrictions on vaccine use, and use of new reporting forms or methods;

6. Maintain all records related to the Nevada State Immunization Program for a **minimum of three (3) years**, and make these records available to public health officials upon request.
 - These records include (but are not limited to) VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering reports which include the monthly "Vaccine Request and Accountability Reports," "Nevada State Immunization Program Temperature Log" or the "Log Tag Report," "Vaccine Incident Reports," "VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine," and the "packing list" received with each vaccine shipment.
7. **Not impose a charge for the cost of the vaccine;**
8. Not collect an administration fee higher than the maximum fee established by the U.S. Centers for Medicare and Medicaid Services for the administration of publicly-supplied vaccine. **The maximum fee allowable in Nevada is \$22.57 per dose administered.**
 - For Medicaid-enrolled children, the provider agrees to accept the administration fee reimbursement set by the state Medicaid agency or the contracted Medicaid health plan.
9. **Not refuse to administer a publicly-supplied vaccine** to an eligible child (established patient) due to the inability of the child's parent, guardian, or individual of record to pay the administration fee;
10. Provide the current Vaccine Information Statement (VIS) to the parent/legal guardian of any child each time the child receives an immunization as required by federal law (42 US Code 300aa-25).
 - Note: VIS's may be downloaded from
: www.cdc.gov/vaccines/pubs/vis/ or <http://www.immunize.org/vis/>;
11. Comply with the requirements for vaccine management and accountability including:
 - a. Ordering vaccine and maintaining appropriate vaccine inventories;
 - b. **Not storing vaccine in dormitory-style units at any time.** For program approved vaccine storage units, please refer to:
 - <http://health.nv.gov/VaccineVFCProgram.htm>
 - <http://health.nv.gov/PDFs/Vaccine/VaccineStorageUnitThingstoConsider.pdf>
 - c. Storing vaccine under proper storage conditions at all times. Refrigerator and freezer storage units and temperature monitoring equipment and practices must meet Nevada State Immunization Program vaccine storage and handling recommendations and requirements, including:
 - Use of a digital, unexpired calibrated thermometer OR digital data logger certified by an ILAC MRA signatory body or which meets ISO/IEC 17025 international standards;
 - Document twice daily the vaccine storage unit's temperature and include actions taken for temperatures found outside the recommended range(s);
 - Receive approval from the Nevada State Immunization Program before moving VFC- or State-supplied vaccine to a newly purchased refrigerator or freezer; and
 - Transport vaccines following industry standards.
 - d. Return all eligible publicly-supplied expired/wasted vaccines **within six (6) months of spoilage/expiration** using the form(s) and instructions provided by the Nevada State Immunization Program;
12. Operate within the Nevada State Immunization Program in a manner intended to avoid fraud and abuse; (*see Fraud & Abuse section for details*)
13. Participate in compliance and unannounced site visits and immunization improvement activities in collaboration with program representatives as requested;
14. Agree to replace vaccine purchased with state (S-CHIP) or federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis;

15. For providers with a current, signed “Deputization Memorandum of Understanding” between a FQHC or RHC and the Nevada State Immunization Program to serve underinsured VFC-eligible children, I agree to:
- Include “underinsured” as a VFC eligibility category during the patient’s screening;
 - Vaccinate “walk-in” VFC-eligible underinsured children; and
 - Report required usage data to the NSIP.

Note: “Walk-in” refers to any underinsured child who presents requesting a vaccine; not just established patients. “Walk-in” does not mean that a provider must serve underinsured patients without an appointment. If a provider’s office policy is for all patients to make an appointment to receive immunizations, then the policy would apply to “walk-in” underinsured patients as well.

16. Utilize Nevada WebIZ, Nevada’s immunization registry, to record all administered vaccinations for children and adults (per **NRS 439.265** and corresponding NAC);
- NRS: www.leg.state.nv.us/NRS/NRS-439.html#NRS439Sec265
 - NAC: <http://www.leg.state.nv.us/Register/2009Register/R094-09A.pdf>
 - WebIZ: http://health.nv.gov/Immunization_WebIZ_Policies_Forms.htm
17. Notify the Nevada State Immunization Program in writing on office letterhead to terminate participation in the VFC Program;
18. **Notify the Nevada State Immunization Program of all changes immediately as they occur, including, but not limited to:**
- Change of address;
 - Change of shipping hours;
 - Change of vaccine contact person;
 - Change of telephone, fax number, or e-mail;
 - Additions/deletions of physicians, PA’s and nurse practitioners to the provider site.

ADDITIONAL REQUIREMENTS FOR PHARMACIES

- Administer publicly supplied vaccine to eligible children only under protocol from a board-licensed prescribing physician;
- Provide the Nevada State Immunization Program with a copy of the written protocol agreement between this facility and a board-licensed prescribing physician;
- Provide a Certificate of Achievement for each registered pharmacist that will be administering vaccine at this location as proof that they have completed a Pharmacy-Based Immunization Delivery Program from the American Pharmacists’ Association; and
- NEVER dispense vaccine to a patient, only administer vaccine on site;
- Vaccinate all “walk-in” VFC eligible children; and
- Do not refuse to vaccinate VFC-eligible children based on a parent/legal guardian’s inability to pay the administration fee.

Note: “Walk-in” refers to any underinsured child who presents requesting a vaccine; not just established patients. “Walk-in” does not mean that a provider must serve underinsured patients without an appointment. If a provider’s office policy is for all patients to make an appointment to receive immunizations, then the policy would apply to “walk-in” underinsured patients as well.

Eligibility Criteria for VFC Vaccines

VFC Eligibility

Only VFC-eligible children can receive VFC vaccines. Children through 18 years of age who meet at least one of the following criteria are eligible to receive VFC vaccine:

- 1) **Medicaid – eligible:** A child who is eligible for the Medicaid program. (For purposes of the VFC program, Medicaid eligible and Medicaid enrolled are use interchangeably and refer to children who have health insurance covered by the state Medicaid program);
- 2) **Uninsured:** A child who has no health insurance coverage;
- 3) **American Indian or Alaska Native (AI/AN):** As defined by the Indian Health Care Improvement Act (25 U.S.C.1603); or
- 4) **Underinsured:**
 - A child who has health insurance, but the coverage does not include vaccines; OR
 - A child whose insurance does not cover all Advisory Committee on Immunization Practices (ACIP) –recommended vaccines. The child would be eligible to receive those vaccines not covered by the insurance.

Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC), or under an approved deputization agreement.

- **Note:** Private providers may receive “Delegation of Authority” from the Nevada State Immunization Program to vaccinate the underinsured children in their office.

Delegation will be assigned to providers at NSIP’s discretion and the provider will be notified when they receive “Delegation of Authority.”

STATE Vaccine Eligibility

Children enrolled in Nevada Check-Up can continue to receive VFC-supplied vaccines. **The VFC Provider MUST document that the child is enrolled in Nevada Check-Up in:**

- The patient’s medical record;
- Nevada WebIZ; AND
- On the NSIP Form 3 – Doses Administered by VFC Eligibility

A child must be screened and documented for VFC eligibility at each immunization visit, prior to immunizing. This screening must be documented in one of the following ways:

- By completing a Patient Eligibility Screening Record. If this is the option the office chooses, then the screening record must be maintained for at least 3 years and is bound by the privacy protection of Federal Medicaid law;
- By making a copy of the child's Medicaid card. The copy must be dated and initialed as current at each immunization visit and filed in the patient’s record. This documentation must be maintained for at least 3 years and is bound by the privacy protection of Federal Medicaid law;
- By completing the Comprehensive Certification Form and submitting it to the Nevada State Immunization Program if a provider or clinic treats only children on Medicaid, American Indian. This form eliminates the need to screen VFC Program participants individually for eligibility and is available upon request;
- By completing the Comprehensive Certification Form and submitting it to the Nevada State Immunization Program if a provider or clinic treats only Native American or Alaska Native children. This form eliminates the need to screen VFC Program participants individually for eligibility and is available upon request;

- By completing the Comprehensive Certification Form and submitting it to the Nevada State Immunization Program if a provider or clinic treats only incarcerated children and they are living in a juvenile detention center. This form eliminates the need to screen VFC Program participants individually for eligibility and is available upon request;
- By updating the VFC Eligibility field on the patient's demographics page in Nevada WebIZ; or
- By using a provider developed screening form that contains the same elements as the CDC approved form.

Vaccine Requests & Accountability

The Nevada State Immunization Program processes enrolled provider vaccine requests monthly. Monthly request deadlines are provided at the end of each month in the e-mailed VFC Monthly Memo. **The amount of vaccine approved is based on the provider's reported monthly usage and a 60-day supply is recommended.** Provider sites are required to submit vaccine inventory and accountability reports monthly, indicating vaccine doses used and doses remaining in physical inventory. Enrolled provider sites must use and submit the most current NSIP reporting forms each month.

Provider Staffing Requirements:

- VFC Providers must designate one staff member to be the primary vaccine coordinator. This individual is responsible for providing oversight for all vaccine management within the office and for ensuring all vaccines are stored and handled correctly.
- A back-up or alternate vaccine coordinator must also be designated who can assume oversight responsibilities in the absence of the primary vaccine coordinator.
- **The primary or backup vaccine coordinator must be the person that completes the vaccine inventory reports each month.**
- **Providers must notify the NSIP when there are any changes in key VFC vaccine staff utilizing the "Vaccine Contact Change Form." Fax the completed form to NSIP at (775) 684-8338 whenever staffing changes occur.**

Completed Forms to be Submitted Each Month by Enrolled Providers:

Form 1: Vaccine Request and Accountability Report

- Complete all the heading information:
 - Facility Name – official name of the facility (do not abbreviate or use the physician's name unless that is the legal name of the practice);
 - Primary Vaccine Coordinator name;
 - Direct Phone Line; and
 - VFC PIN; and
 - Check the "VFC" box;
- Reporting period (always begins the first day of the month and ends the last day of the month);
- Denote "Beginning Inventory" (this is the beginning inventory on the 1st day of the month and is the same as the "End of the Month Refrigerator Count" for the previous month). Do not include privately purchased vaccines on VFC reporting forms;
- Denote "Doses Received" (these are the vaccines received from McKesson);
- Denote "Doses Transferred In", if applicable (these are VFC vaccines received from another VFC enrolled provider);
- Denote "Doses Administered" (how many doses of VFC/state supplied vaccine the facility administered during the month);
- Denote "Doses Transferred Out", if applicable (these are VFC vaccines the facility transferred to another VFC enrolled provider);
- Denote "Doses Expired or Wasted" (these are VFC/state vaccines that expired or were spoiled/wasted and must be returned to McKesson using the proper paperwork);

- Denote “Ending Inventory” (this is the calculation of adding column #1 plus column #2, plus column #3, minus column #4, minus column #5, minus column #6 and the result is the facilities ending inventory for the month);
- Denote “End of Month Refrigerator Count” (this is the physical count of VFC doses in the vaccine storage unit at the end of the month). If the physical count does not match the “Ending Inventory,” then the accountability paperwork must be reviewed and corrected;
- **Denote the number of doses requested (not number of boxes); and**
- **Please note that any discrepancies between the ending inventory calculation and the physical vaccine dose count will be considered wasted vaccine.**

Form 2: Vaccine Lot Number Inventory Report

- Complete all the heading information:
 - Facility Name – official name of the facility (do not abbreviate or use the physician’s name unless that is the legal name of the practice);
 - Primary Vaccine Coordinator name;
 - Direct Phone Line;
 - VFC PIN; and
 - Check the “VFC” box
- Reporting period (always begins the first day of the month and ends the last day of the month);
- **You must report completely and accurately each lot number of VFC/state supplied vaccine that you have on hand on the last day of the month;**
 - There is room to list up to three (3) lot numbers of any given vaccine on this form; if you have more than three (3) lots of any given vaccine, then you must use a second Form 2 sheet;
- The dose amounts listed in the “Total Inventory” column of Form 2 must match the “End of Month Refrigerator Count” on Form 1.

WebIZ Vaccine Inventory Reconciliation Report

- Type 3 WebIZ users may use this form in lieu of Form 2 to report vaccine lot numbers and inventory
 - Complete your inventory count in WebIZ;
 - Close your reconciliation;
 - Print these forms out and submit with your monthly reports
- The dose amounts listed in the “Ending Balance” column of the reconciliation report must match the “End of Month Refrigerator Count” on Form 1.

Nevada WebIZ “Doses Administered by VFC Eligibility” Report

- As a vaccinating provider, you are required by state law to enter all vaccine doses administered by your practice into Nevada WebIZ. **The “Doses Administered by VFC Eligibility” report replaces Form 3: “Eligibility Report of Doses Administered.”**
 - This report can be located under the “Reports” section on the left side of the Nevada WebIZ home page, and then under the “Coverage Statics” section.
 - Under the vaccination range dates, fill in the dates using the first day of the month through the last day of the month for which you are reporting.
 - Data in this report is populated from the information entered by the practice in Nevada WebIZ.
 - Print this report and submit it with your monthly vaccine request in lieu of Form 3.
- Providers entering data into Nevada WebIZ via HL7 interface will not be able to access this report, so you will need to continue to manually complete Form 3.

Form 3: Eligibility Report of Doses Administered (For HL7 Submitters Only)

- Complete all the heading information:
 - Facility Name – official name of the facility (do not abbreviate or use the physician's name unless that is the legal name of the practice);
 - Primary Vaccine Coordinator name;
 - Direct Phone Line;
 - VFC PIN; and
 - Check the "VFC" box;
- Reporting period (always begins the first day of the month and ends the last day of the month);
- **Make a blank copy of this report to use as a worksheet. As each dose is drawn, make a tic mark for that dose in the corresponding cell and category;**
 - Document similar vaccine doses from different manufacturers into one cell/category/row. There is no need to document all the different doses per manufacturer separately. In addition, there is no need to add any rows to the form;
- Add the tic marks on the worksheet at the end of the month and **place the whole number in each corresponding cell** on a blank form for faxing to the Nevada State Immunization Program; and
- **Do not fax this form to the Nevada State Immunization Program with tic marks, or it may be returned to you for correction.**

Digital Data Loggers for Continuous Temperature Monitoring:

The NSIP is providing all enrolled VFC offices with a thermometer product called the LogTag TRED 30-7R. This continuous temperature monitor provides 24-hour recorded monitoring. The following protocol reviews the procedure for using this product to monitor VFC storage units.

- Data Loggers must be physically checked twice daily. During the morning check, min/max temperatures must be reviewed:
 - Leaving the probe plugged into the unit, review the min/max temperature:
 - Press the "Review" button to obtain the "max" temp recorded for the past 24 hours;
 - Press the "Review" button again to obtain the "min" temp recorded for the past 24-hours
 - Press the Start/Clear/Stop button to refresh the display and show current temperatures
 - Initial, date and write time down on the Temperature Check Form that you have checked the temperatures on both storage units.
- **If there was an out-of-range temperature reading in the past 24 hours, the word "ALARM" will be present on the screen above the current temperature display. Take immediate action if this occurs:**
 - **STOP VACCINATING PATIENTS!**
 - Move the vaccine to proper storage conditions as quickly as possible keeping it separate from other vaccines and mark it "Do Not Use";
 - Stop the recorder by holding the "Stop" button until the word "Stopping" quits flashing, then unplug the probe;
 - Place the Log Tag recorder in the USB interface and download the information;
 - Send the data to nviz@health.nv.gov and notify the NSIP Vaccine Manager that you;
 - Call the vaccine manufacturer(s) to determine the viability of the vaccine;
 - Document the "Disposition" per manufacturer on the "Vaccine Incident Report"; and
 - Fax the completed report to the NSIP at (775) 684-8338.

Form 4: Nevada State Immunization Program Temperature Log

Complete all the heading information:

- VFC PIN;
- Facility Name – official name of the facility (do not abbreviate or use the physician's name unless that is the legal name of the practice); and
- Current Month and Year;
- Use a separate "Temperature Log" for each vaccine storage unit that holds VFC/state supplied vaccines;
- Write in the time you are checking the temperature;
- Place an "X" in the box that corresponds with the current temperature and time of day (i.e, AM/PM) as well as the initials of the staff member recording the temperature;
- **FOR OFFICES WITH MIN/MAX THERMOMETERS:** During each morning reading place an "O" in the box that corresponds with the maximum and minimum temperature reached since the last reset, and then reset the max/min function for the next morning;
- There are many types of min/max thermometers on the market. If you need assistance resetting the min/max on your thermometer, then please contact the NSIP Vaccine Manager;
- Write on the bottom right side of the form the expiration or recalibration date(s) for each thermometer used to monitor a vaccine storage unit that contains VFC/state supplied vaccines; and
- **Take immediate action if the temperature you record is in the shaded zone as this represents an unacceptable temperature range and will damage the vaccines:**
 - Move the vaccine to proper storage conditions as quickly as possible keeping it separate from other vaccines and mark it "Do Not Use";
 - Call the Nevada State Immunization Program at (775) 684-5900;
 - Begin completing the "Vaccine Incident Report";
 - Call the vaccine manufacturer(s) to determine the viability of the vaccine;
 - Document the "Disposition" per manufacturer on the "Vaccine Incident Report"; and
 - Fax the completed report to the NSIP at (775) 684-8338.

Submitting Vaccine Requests:

- Each month fax to the Nevada State Immunization Program at (775) 684-8338:
 - Form 1: Vaccine Request and Accountability Report;
 - Form 2: Vaccine Lot Number Inventory Report **OR** the Nevada WebIZ generated Reconciliation Report;
 - Form 3: Eligibility Report of Doses Administered **OR** the Nevada WebIZ generated "Doses Administered by VFC Eligibility" report; and
 - Form 4: Nevada State Immunization Program Temperature Log **OR** the LogTag temperature download if applicable.
- Incomplete reports will be returned for correction which could result in the vaccine request being placed on hold.
- Emergency requests are allowed only during "outbreak" situations.
- Vaccines should arrive within ten (10) days after the Vaccine Request Confirmation is received by the provider.
- **Providers should maintain a 60-day supply of public vaccine inventory.**
- If it is necessary for the office to submit a second vaccine request (e.g., you forgot to ask for something, etc.), then you must write "Supplemental" on the margins of Form 1 when you send in the supplemental request. **If you fail to notify us that a request is supplemental to paperwork you have already submitted, then the supplemental request will be discarded.**

Vaccine Borrowing Guidance

CDC's expectation is that VFC-enrolled providers maintain adequate inventories of vaccine to administer to both privately insured and VFC-eligible children. Borrowing of vaccine must be due to unforeseen delays or circumstances surrounding the vaccine that was ordered. Scheduling of a mass immunization clinic without having appropriate amounts of both public and privately purchased vaccine available on-hand for the expected participants would not be considered an unexpected circumstance.

The Borrowing Report must be completed in all settings for all vaccine borrowed in either direction. The Borrowing Report must be completed when either:

- Privately-purchased vaccine is administered to a VFC-eligible child, or
- VFC vaccine is administered to a privately-insured child.

The VFC Provider must document:

- Why the vaccine was borrowed, and
- The date the vaccine was replaced and the inventory was made whole

Borrowing activities must be monitored as part of the VFC compliance visit. Questions regarding borrowing have been included in the VFC Site Visit Questionnaire. Follow-up and/or corrective actions will be taken when excessive or inappropriate borrowing activities are noted.

- **VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory.**
- VFC vaccine supply must adequately meet the needs of your VFC-eligible patients. Borrowing of VFC vaccine must not prevent a VFC-eligible child from receiving a needed vaccination because the VFC vaccine was administered to a non-VFC eligible child.

Borrowing of vaccine between two vaccine inventories must be a rare, unplanned occurrence. Borrowing can occur only when there is:

- A lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment;
- Vaccine spoiled in-transit to provider; OR
- New office staff (at the provider or NSIP level) that calculated ordering time incorrectly.

Seasonal influenza Vaccine Borrowing:

- For seasonal influenza, VFC providers may use private-stock influenza vaccine to vaccinate VFC-eligible children if VFC influenza vaccine is not yet available. Those private stock doses used on VFC-eligible children can later be replaced when VFC stock becomes available. This **one-directional borrowing exception** is unique to seasonal influenza vaccine.

Borrowing Of Vaccine to Prevent Loss Due To Expiration:

This two-way exchange can be used by a VFC-enrolled provider with a patient population that is mostly VFC-eligible. This means the provider has a small number of privately insured children.

Privately purchased vaccine that is short-dated may be administered to a VFC-eligible child, and the dose replaced with a longer-dated VFC dose.

- **Providers must document any vaccine borrowing on the Vaccine Borrowing Form regardless of inventory origin (VFC vs. Private).**
 - If a provider borrows privately purchased vaccine to administer to a VFC-eligible child because no VFC vaccine is available or if VFC stock is borrowed, then the provider must document that borrowing and replacement activity on the VFC Borrowing Form. This action is to ensure that the private-stock or VFC-stock is replaced and the inventory is made whole.
 - Once the borrowed vaccine is replaced, the replacement date must be entered on the VFC Borrowing Form.
 - The completed form must be saved and submitted to the NSIP for review with a copy of the invoice proving stock replenishment occurred.

Proper Vaccine Storage and Handling

Vaccine Storage and Handling Guidelines:

Vaccine storage units must be selected carefully and used properly. **Stand-alone refrigerators and freezers are the only units proven to consistently maintain required temperature ranges for safe vaccine storage.** However, a combination refrigerator/freezer unit with two doors and two thermostat controls is acceptable for vaccine storage if only the refrigerator compartment is being used to store vaccine. Combination units do not maintain consistent temperatures for the freezer compartment. The Centers for Disease Control and Prevention (CDC) recommends that any refrigerator or freezer being used for vaccine storage must:

1. **Be able to continuously maintain required vaccine storage temperatures;**
 2. **Be large enough to hold the year's largest inventory (think back to school and flu season);**
 3. **Be monitored using an unexpired, calibrated digital data logger thermometer; and**
 4. **Be dedicated to the storage of vaccines or other biologics. No food or beverages should be stored in a vaccine storage unit.**
- **Beginning January 1, 2015 – If the NSIP Program Manager, Vaccine Manager, Provider Quality Assurance Manager, and/or the Vaccine Storage & Handling Coordinator has recommended to a VFC-enrolled provider's Primary Vaccine Coordinator and/or Medical Director that the provider should purchase stand-alone refrigerator and freezer units as a result of reviewing long-term temperature monitoring information, and the office does not purchase the recommended storage unit type, then the provider WILL be held accountable for replacing all VFC vaccine doses (at private cost) that are spoiled or wasted as a result of temperature excursions in the non-recommended unit.**

General Requirements:

Vaccines that require storage temperatures between **35° and 46°F (2° and 8°C)** must be stored in the refrigerator compartment of a household- or commercial-style refrigeration unit. Vaccines that require storage temperatures of **5°F (-15°C) or colder** should be stored in a stand-alone freezer. Frozen vaccines include MMR-V (Proquad), Varivax and Zostavax. **It is strongly recommended that VFC provider offices use separate units for vaccine storage, because stand-alone refrigerators and freezers maintain the required temperatures better than home-style combination units.** If a combination unit is used, then the refrigerator and freezer compartments must have separate external doors and separate thermostat controls. The storage unit must have enough room to store the year's largest vaccine order without crowding and without the vaccines touching the back or sides of the unit's interior. It is recommended to store full water bottles in the refrigerator and frozen ice packs in the freezer to help stabilize the temperature and assist in keeping the compartments cold in cases of power outage or mechanical failure.

Reminder: Vaccines are not to be stored in the door of a unit or in the crisper drawers.

For more information on vaccine storage go to:

www.cdc.gov/vaccines/recs/storage/default.htm

Unacceptable Vaccine Storage Units:

The following units are unacceptable for vaccine storage, even temporarily, no exceptions:



- **“Dorm-style” units** provide poor temperature control and often freeze vaccines that require refrigeration, resulting in immediate and irreversible damage. “Dorm-style” units are defined as small refrigerator/freezer combination units with a single external door and an evaporator plate or cooling coil that forms a small freezer compartment within the unit or is pulled across the internal back wall of the unit.

- Manual defrost (or cyclic defrost) refrigerators have significant temperature variations, often freezing and damaging vaccines. These units often have exposed cooling plates, coils or vertical plates in the interior back wall of the refrigerator. These may be covered with visible frost or ice.
- Convertible refrigerator-only units that have an internal switch to convert the “refrigerator-only” unit to a “freezer-only” unit.
- **Any refrigeration/freezer unit that is over 10 years old.**
- Small apartment size (4ft or below) units.

Dorm-Style Units: Small, single-door combined refrigerator/freezer units **cannot** be used for any vaccine storage, even temporarily. The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store frozen vaccines. If attempts are made to cool the freezer to the appropriate temperature, then the temperature in the refrigerator will fall below the recommended range, potentially freezing the refrigerated vaccines.

Acceptable Vaccine Storage Units:

The following types of units are accepted by the Nevada State Immunization Program:

- Stand-alone refrigerator unit(s) – **recommended type**;
- Stand-alone freezer unit(s) – **recommended type**;
- Combination refrigerator/freezer unit with two doors and **two** thermostat controls;
- Combination refrigerator/freezer unit with two doors and **one** thermostat control, where only the refrigerator compartment is being used for vaccine storage; and
- Commercial combination self-defrosting unit with two separate compressors, a thermostat control for each compartment, and no circulating air between the freezer and refrigerator compartments.
- It is **highly recommended** if a combination refrigerator/freezer unit with two doors and either one or two thermostats are used, a separate stand-alone freezer be used for frozen vaccine. Freezer sections in these combination units are not capable of reliably maintaining appropriate frozen vaccine storage temperatures.

Option 1: Stand-Alone, Under-the-Counter Refrigerator and Freezer Units

Stand-alone, under-the-counter refrigerators and freezers are excellent choices for vaccine storage. Under-the-counter refrigerators and freezers are stand-alone units that allow for the separate storage of frozen and refrigerated vaccines. Stand-alone refrigeration units must also be self-defrosting and it is recommended that stand-alone freezer units be self-defrosting.



The benefits of using stand-alone units for vaccine storage include:

- **Lower risk of catastrophic inventory loss:** Separate compressors and condensers decrease the risk of total vaccine loss that might occur in a combination style unit.
- **Temperature stability:** Because these units are only required to hold a single set temperature, they are not constantly re-adjusting and circulating cold air between the refrigerator and freezer compartments.
- **No risk of accidentally freezing refrigerated vaccine:** Combined units often use a cold air vent from the freezer to regulate temperatures in the refrigerator compartment. This freezing air blows down on the top shelf of the refrigerator and can quickly freeze any vaccines stored underneath.

Providers have many options for finding affordable, office-appropriate stand-alone units. **Stand-alone units can be under-the-counter size as discussed here or full-size.** VFC Providers and office managers can shop local home improvement stores (Home Depot, Lowes) or opt for lab/pharmaceutical grade units (Panasonic, Amer Biotech Supply, Migali):

- <http://www.homedepot.com/> - search within appliances
- <http://www.lowes.com/> - search within appliances
- http://www.panasonic.com/business/healthcare/biomedical/vaccine/?_kk=5ce24da0-8f0d-46d9-a4fc-9e7e44de6fe5&_kt=16601245831
- <http://www.americanbiotechsupply.com/>
- <http://www.migaliscientific.com/products/vaccine-storage/>

Option 2: Home-Style. Combination Refrigerator/Freezer Units

These types of units are most often found in home and appliance stores. Higher-end models are sometimes referred to as “commercial-grade” and are most often used in the food service industry. While not ideal for vaccine storage, many immunization clinics use this type of unit due to its affordability. **In 2015, VFC providers that will be replacing a vaccine storage unit must purchase a stand-alone unit to remain VFC compliant.** If your office is still using a home-style combination unit for VFC vaccine storage, then it must incorporate the characteristics detailed below.

Essential features for a combination unit:

- Refrigerator and freezer compartments must have separate external doors;
- Refrigerator and freezer compartments must each have a dedicated thermostat control;
- The shelves should be adjustable; and
- There should be enough room to store vaccine on the middle shelves (away from cool air vents).
- It is highly recommended that a separate stand-alone freezer be used to store frozen vaccine and the refrigerated vaccine can then be stored in the refrigerator section.



Recommended features for a combination unit:

- Outside door locks (manufacturer installed only);
- Separate compressor units for each compartment;
- Automatic condensate removal, no drain lines;
- Forced air circulation;
- Door alarm if left open or ajar; and
- Battery back-up (in cases of power failure).

Risk of freezing vaccine – Never store freeze-sensitive vaccines near the cold air vent in the refrigerator compartment; cold air from the freezer will often blow down on the vaccine and freeze it, resulting in irreparable damage and wasted vaccine.

Single thermostat units – Home-style, combination refrigerators with a single thermostat are strongly discouraged. This type of unit is only acceptable if storing vaccine in the refrigerator compartment only. A single thermostat makes it difficult to maintain recommended temperatures in both compartments. **If you are thinking of purchasing a new vaccine storage unit, then call the NSIP Vaccine Manager at 775-684-3462.**

Option 3: Stand-Alone, Laboratory Grade Refrigerator and Freezer Units

Stand-alone, laboratory grade refrigerators and freezers are considered the gold standard for dedicated vaccine storage; they are considered the most secure. As with most “gold-standard” products, they carry a hefty price tag and are usually reserved for health departments, laboratories and hospitals. However, many manufacturers also produce an array of refrigerators and freezers that may meet your clinic’s specific vaccine storage needs. **Be aware that units with glass-front doors do not maintain cold temperatures during power outages as well as units with solid doors.**



Products and vendors are referenced for informational purposes only; listing in this document does not imply endorsement by the National Immunization Program (NIP) nor the Nevada State Immunization Program of the vendor or products listed.

TEMPERATURE MONITORING REQUIREMENTS IN NEVADA

Beginning January 1, 2015, VFC providers are required to purchase at their expense at least one back-up thermometer with a current certificate of calibration and have it readily available. This is to be used if the current temperature monitoring system fails or needs to be sent in for re-calibration.

If your office has not yet been provided a digital data logger, then the thermometer that is used to monitor VFC vaccine storage units must:

- Have a digital display that can be read without opening the unit doors;
- Have a biosafe glycol-encased probe or similar buffer style probe;
- Have current temperature, minimum/maximum temperature review functionality;
- Have an alarm (audible or visual) for out-of-range temperatures;
- Have an accuracy of $\pm 1^{\circ}\text{F}$ (0.5°C); and
- Have a low battery indicator.

It is strongly recommended that clinics that are routinely closed for more than 2 consecutive days, and do not have office staff that assess and records temperatures twice a day on days when the office is closed, use digital data loggers with continuous monitoring and recording capabilities.

Biosafe Glycol-Encased Probes or Similar Temperature Buffered Probes:

The Centers for Disease Control and Prevention (CDC) **recommend use of a digital thermometer with a biosafe glycol-encased probe or a similar temperature buffered probe that will more closely approximate the measure of liquid temperature.** A temperature buffer enables a thermometer probe to more closely match the temperature changes experienced by liquid vaccine.

Examples of temperature buffers are a probe inserted into a glycol-filled vial or one inserted into glass beads. **The Nevada State Immunization Program requires this type of probe because studies by the National Institute of Standards and Technology (NIST) conducted in 2009 showed that compared to temperature monitors that measure ambient air temperature, the digital thermometer with glycol-encased probe more accurately reflects the temperature of the vaccine vial and does not register normal air temperature fluctuations which do not significantly impact vaccine temperature.**

Because the main factor affecting potency of refrigerated vaccines is exposure to freezing temperatures, it is important that glycol-encased or similar temperature buffered probes be placed among the vaccines in a central portion of the unit instead of on a unit's wall, and at least for refrigerated vaccines, in the part of the refrigerator where manufacturer recommended vaccine storage temperatures can best be maintained.

In addition to the use of a digital thermometer in a glycol-filled vial, the recommended temperature monitor should also provide continuous data monitoring information in an active display and be placed on the outside of the unit to allow for reading temperatures without opening the unit door.

Thermometer Calibration Requirements:

To ensure validity of temperature measurements, only calibrated thermometers with a certificate of Traceability and Calibration performed by a laboratory accredited by an ILAC-MRA signatory body or an entity that provides documentation showing calibration testing that meets ISO/IEC 17025 international standards should be used. Calibrated thermometers will continue to be a requirement for providers who receive VFC vaccine.

Digital Data Loggers for Temperature Monitoring:

The Nevada State Immunization Program is providing all enrolled VFC providers with at least two (2) LogTag TRED30-7R data loggers by the end of 2015.

In addition to the use of a digital thermometer with a biosafe glycol-encased or similar temperature buffered probe, the thermometer should also be able to provide and store data monitoring information set at programmable intervals in an active display that allows for reading temperatures without opening the unit door. This means that the digital data logging thermometer probe should be able to remain in place and not be disturbed during data reading and recording. A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and should simplify daily use and minimize operator cause of temperature variability. The digital data logger should also include the following:

- ☐ Hi/Lo alarm for out-of-range temperatures;
- ☐ Current temperature, as well as min/max temperatures;
- ☐ Reset button;
- ☐ Low battery indicator;
- ☐ Accuracy of +/- 1°F (0.5°C);
- ☐ Memory storage of at least 4000 readings, the device cannot rewrite over old data, and it stops recording when memory is full; and
- ☐ User programmable logging interval (or reading rate).

Refrigerated Vaccines:

The temperature of all refrigerated vaccine must remain steady between 35°F and 46°F (2°C and 8°C). **The recommended temperature for refrigerated vaccines is 40°F.** The vaccines are shipped with ice packs and bubble wrap to protect the vaccines from contact with the frozen ice packs.

Frozen Vaccines:

Frozen vaccines are shipped by the manufacturer directly to the provider site with frozen gel packs. All frozen vaccines must be stored at temperatures between 5°F and -58°F (-15°C and -50°C) until reconstitution and use. **The recommended temperature for frozen vaccines is 3°F or lower.**

Temperature Checks:

Refrigerator and freezer temperatures must be checked a minimum of twice daily on business days using one of two methods:

- Option 1: Document temperatures on the graph-style Form 4: Nevada State Immunization Program Temperature Log. It is required that providers be using a thermometer that includes a minimum/maximum function. The minimum and maximum temperatures must be recorded on the Temperature Log each morning and reset to be checked the next morning of business. Providers are required to maintain temperature logs on file for at least three (3) years.
- Option 2: Using a continuous temperature monitoring and recording system (Log Tag provided by NSIP).

Reimbursement/Restitution:

The Nevada State Immunization Program may request a dose-for-dose reimbursement from an enrolled provider for the value of vaccines wasted through negligent storage practices that do not meet program requirements. If charged, providers will have 90 days to demonstrate that all doses were replaced appropriately.

Additional Requirements for Proper Vaccine Storage and Handling:

- The provider must have on-site a current "Office Vaccine Management Plan." A template can be located on our website, http://health.nv.gov/Vaccine_VFCProgram.htm;
- The "Office Vaccine Management Plan" should be reviewed at least annually and a "Reviewed Date" put on it to ensure they are current;
- Food must not be stored in any refrigerator(s) or freezer(s) being used for vaccine storage;
- Vaccines must not be stored in the drawers, doors, or crisper drawer area;
- Vaccines stored in a combination refrigerator unit must be far enough away from the air venting from the freezer compartment to avoid freezing the vaccines;
- Vaccines must be stacked with at least 2 inches of air space between the boxes and the side/back walls of the storage unit to allow air to circulate around the vaccine;
- Vaccine must be stored in the original box until use;
- Bottles of water should be stored in the lowest compartment of the refrigerator and extra ice packs stored in the freezer to help maintain temperatures in case of a power outage. No ice packs in the doors of the freezer;
- VFC/state vaccine may be stored in the same unit as privately purchased vaccine, but must be clearly labeled as "VFC" for easy identification by office staff;
- Inventory must be rotated to ensure that the shortest dated vaccine is used first;
- VFC/state supplied vaccine with short expiration dates (expiring within 3 months) should be reported to the Nevada State Immunization Program if the provider site does not anticipate using them before they expire. When notified that short-dated vaccines will not be used before expiration, the Nevada State Immunization Program will make every effort to have the vaccines transferred to another enrolled provider for immediate use;
- Post "Do Not Disconnect" signs on the front of each vaccine storage unit, next to the storage units' electrical outlet (if exposed) and on the breaker switch that supplies power to the vaccine storage unit(s);
- The vaccine storage unit must be plugged directly into an electrical outlet (**surge protectors are not permitted**); and
- Provider office staff responsible for VFC vaccine storage and handling should review and apply the practices for proper storage and handling found at: <http://www.cdc.gov/vaccines/recs/storage/default.htm>

Receiving Vaccine Shipments:

All staff in the facility must be trained in vaccine receipt and management (including, but not limited to):

- Front desk staff
- Medical staff
- Purchasing staff
- Security staff, etc.

All staff who may accept packages for the clinic must be aware that vaccine shipments require immediate attention

In order for shippers to deliver vaccines, provider staff must be on site and available to receive vaccine at least one day a week other than Monday, and for four consecutive hours during that day.

Receiving Refrigerated Vaccines:

- The staff person accepting the shipment must immediately notify the office's primary vaccine coordinator or the designated backup;
- The box containing the vaccines must be physically handed to the office's primary vaccine coordinator or the designated backup;
- Immediately upon shipment receipt, remove both temperature monitors included in the shipment:
 - 3M MonitorMark to determine if the shipment may have been subjected to warmer temperatures; and
 - TransTracker C FREEZEmarker Indicator to determine if the shipment may have been subjected to colder temperatures.
 - Follow the monitor instructions on each card regarding activation and reading; and
 - **If you have any questions or concerns when reading the monitor, if the monitor is not activated, or if you see damage to the package, then contact McKesson Specialty Contact Center (MSCC) at 877-836-7123 within 2 hours and notify the Nevada State Immunization Program;**
- Check the condition of the vaccines;
- Determine the length of time the vaccine was in transit by looking at the packing list;
- Compare the "packing list" to the actual contents of the shipment. Any discrepancies and/or damage must be reported immediately to the Nevada State Immunization Program at (775) 684-5939;
- If there are any discrepancies with the packing slip or concerns about the shipment, then immediately mark the vaccine and diluents as "DO NOT USE" and store them in proper conditions; and
- **Refrigerate the vaccines immediately and place those with the shortest expiration date in front to be administered first.**

Receiving Frozen Vaccines:

- The staff person accepting the shipment must immediately notify the office's primary vaccine coordinator or the designated backup;
- The box containing the vaccines must be physically handed to the office's primary vaccine coordinator or the designated backup;
- Immediately upon shipment receipt, check the condition of the vaccines and the packaging for damage;
- Compare the "packing list" to the actual contents of the shipment. Any discrepancies and/or damage must be reported immediately to the Nevada State Immunization Program at (775) 684-5939;
- Check the condition of the vaccines;
- Determine the length of time the vaccine was in transit by looking at the packing list.
 - An adequate number of gel packs are placed in the shipping container to maintain proper temperatures for THREE (3) DAYS from the shipment date located on the packing list. If the shipment is received after this time period, then contact the Merck Order Management Center immediately for replacement at 800-637-2579.
- Contact the Nevada State Immunization Program immediately if there is any damage and/or discrepancies at (775) 684-5939; and
- **Immediately store the vaccines in the freezer with the shortest expiration date in front to be administered first.**

If Vaccines Have Been Exposed to Improper Temperatures at Provider's Location:

- Immediately place the vaccine into proper storage conditions and label "Do Not Use";
- Do not presume that the vaccine has been compromised;
- Contact the Nevada State Immunization Program at (775) 684-5939;
- Begin completing the "Vaccine Incident Report";
- Call the manufacturers to assess whether vaccine potency could have been affected;
- Document viability and disposition per manufacturer on the "Vaccine Incident Report";
- Document corrective action steps taken on the "Vaccine Incident Report"; and
- Fax the completed "Vaccine Incident Report" to the Nevada State Immunization Program at (775) 684-8338.
- If the vaccines are determined to be non-viable by the manufacturer, then follow the instructions below regarding "Steps for Returning Expired/Spoiled Vaccine to McKesson."
- **If the Nevada State Immunization Program determines that adversely affected vaccines were administered after exposure to damaging storage conditions, then the NSIP requires VFC providers to contact the patients/parents/guardians of the vaccine recipients and offer re-vaccination to ensure they are appropriately immunized.**

IMPORTANT STORAGE INSTRUCTIONS ABOUT VARIVAX® (VARICELLA Virus Vaccine Live) & ZOSTAVAX (ZOSTER Vaccine Live):

Merck has replaced the use of dry ice with frozen gel packs in the shipping packages for VARIVAX and ZOSTAVAX. **An adequate number of gel packs were placed in this shipping container to maintain proper temperatures for THREE (3) DAYS from the shipment date located on the packing list. The responsible primary vaccine coordinator or designated backup must immediately open the container and store the vaccine in a freezer.**

VARIVAX and ZOSTAVAX are packed with frozen gel packs in the shipping container. Upon delivery, the gel packs should feel cold and may be pliable to the touch. The quantity of gel packs placed in the container is based on carefully determined guidelines. These Merck guidelines take into account the maximum temperature to which the container will be exposed, the time in transit, and the need to keep the vaccine at the appropriate temperature during shipping. Product shipped with the gel packs may not be as cold as product previously shipped with dry ice.

If the container is received after the time period described above, then contact the Merck Order Management Center immediately for replacement instructions at 800-637-2579 and notify the Nevada State Immunization Program. Such requests for replacement must be received by Merck within 15 days of receipt of the original shipment.

- The vaccine is located in the lower compartment of the package – **Store the vaccine in a FREEZER immediately.** Any freezer, including frost-free, that has a separate sealed freezer door and reliably maintains a temperature between –58°F and +5°F (–50°C to –15°C) is acceptable.
- Merck does not recommend re-use of shipping materials, including gel packs and shipping containers to further transport vaccine products as improper re-packaging and transportation could impact the stability of the vaccine.
- The gel packs contain water-based non-toxic gel. Please dispose of these gel packs with regular trash.
- Store the diluent (located in the top compartment of the package underneath the cardboard cap) in a refrigerator [36°F to 46°F (2°C to 8°C)] or at room temperature [68°F to 77°F (20°C to 25°C)].

Checklist for Safe Vaccine Handling and Storage

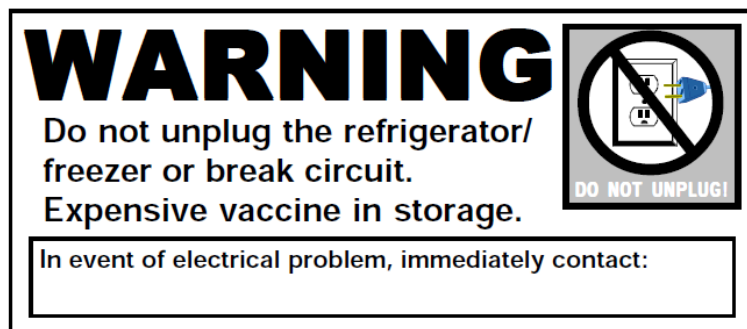
Here are the 20 most important things you can do to safeguard your vaccine supply. Are you doing them all?
Reviewing this list can help you improve your clinic's vaccine management practices.

YES	NO
	1. We have a designated person in charge of the handling and storage of our vaccines.
	2. We have a back-up person in charge of the handling and storage of our vaccines.
	3. A vaccine inventory log is maintained that documents: _____ Vaccine name and number of doses received _____ Date the vaccine was received and length of time it was in transit _____ Arrival condition of vaccine _____ Vaccine manufacturer and lot number _____ Vaccine expiration date.
	4. Our refrigerator for vaccines is either household or commercial-style, NOT dormitory-style. The freezer compartment has a separate exterior door and separate thermostat control. Alternatively, we use two storage units: a free-standing refrigerator and a free-standing freezer.
	5. We do NOT store any food or drink in the refrigerator or freezer.
	6. We store vaccines in the middle of the refrigerator or freezer, and NOT in the door.
	7. We stock and rotate our vaccine supply so that the vaccine with the closest expiration date used first.
	8. We check vaccine expiration dates and we first use those that will expire soonest.
	9. We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
	10. We always keep an unexpired, calibrated thermometer in the refrigerator.
	11. The temperature in the refrigerator is maintained within a range of 35°F to 46°F (2°C to 8°C).
	12. We keep extra containers of water in the refrigerator to help maintain cold temperatures.
	13. We always keep an unexpired, calibrated thermometer in the freezer.
	14. The temperature in the freezer is maintained at a range of 5°F to -58°F (-15°C to -50°C).
	15. We keep ice packs and other ice-filled containers in the freezer to help maintain cold temperatures.
	16. We post a temperature log on the refrigerator door on which we record the refrigerator and freezer temperatures twice a day – first thing in the morning and at clinic closing time – and we know whom to call if the temperature goes out of range.
	17. We have a “Do Not Unplug” sign on the vaccine storage unit and/or next to the refrigerator's electrical outlet.
	18. In the event of a refrigerator failure, we take the following steps: _____ We assure that the vaccines are placed in a location with adequate refrigeration _____ We mark exposed vaccines and separate them from undamaged vaccines _____ We note the time and the refrigerator or freezer temperature and contact the vaccine manufacturer or state health department to determine how to handle the affected vaccines - We follow the vaccine manufacturer's or health department's instructions as to whether the affected vaccines can be used, and, if so, we mark the vials with the revised expiration date provided by the manufacturer or health department.
	19. We have a detailed written policy for general and emergency vaccine management and reviewed periodically to verify they are current.
	20. If all above answers are “YES,” we are patting ourselves on the back. If not, we have assigned someone to implement needed changes!

Setting Up Your New Vaccine Storage Unit

Before placing vaccines in a new unit, follow these simple steps to ensure success:

- Make arrangements in advance to temporarily store your vaccines in an appropriate, alternate storage unit with calibrated thermometers. Monitor the temperature of this temporary unit a minimum of twice daily and maintain stable temperature readings within the target ranges (refrigerator: 40°F and freezer: 5°F or <5°F) until the new unit is approved for vaccine storage;
- **Monitor the temperature of the new unit twice daily for at least five (5) business days before placing vaccines within. Obtain approval from the Nevada State Immunization Program prior to transferring vaccines into the new unit;**
- Your new unit may have colder and warmer areas especially in the refrigerator compartment. A best practice is to check the temperatures in different areas of the compartment prior to vaccine storage in order to determine the most stable area for vaccine storage;
- Plug the new vaccine storage unit directly into a wall or floor outlet. **Never use extension cords or power strips;**
- If your new unit comes with vegetable bins, then fill them with full bottles of water. **Do not store vaccines in the refrigerator doors, vegetable bins, or on the floor of the unit;**
- Add additional full bottles of water to the shelves inside the refrigerator door and store ice packs in the freezer. These measures will help maintain a stable, cold temperature if the refrigerator or freezer doors are opened frequently or in cases of power failure;
- Place digital, unexpired calibrated thermometers (with glycol-encased probes) in the center of each compartment close to where the vaccine will be stored. Any thermometer being used, including built-in thermometers in pharmacy and lab-grade units, must have a certificate of calibration proving it has been calibrated by an ILAC-MRA signatory body, or an entity that provides documentation that the calibration testing meets ISO/IEC 17025 standards for calibration testing and traceability;
- Set the refrigerator temperature to stabilize around 40°F and set the freezer temperature to stabilize around 3°F or lower. Adjust the temperature in small increments and continue to monitor the units until the target temperatures are reached;
- Carefully label the areas where you will be storing vaccine. Identify where publicly supplied vaccine will be stored versus where privately purchased vaccine will be stored; and
- Be sure a DO NOT UNPLUG sticker is posted on the front of the unit(s), near the electrical outlet(s), and label the appropriate circuit breaker(s): "Expensive Vaccines, Do Not Disconnect."



Returning Expired/Wasted Vaccines

The Following Items Should NEVER Be Returned to McKesson:

- Syringes that you filled but did not use;
- Any used syringes with or without needles attached;
- Broken vials; or
- Any multi-dose vial from which some doses have been withdrawn.



The items listed above should be disposed of according to usual medical biosafety procedures.

Do not return empty shipping boxes to McKesson Specialty Distribution Center. Providers are encouraged to recycle the boxes through their local recycling programs. McKesson Specialty Distribution Center recommends that providers keep one or two boxes on hand for use in returning non-viable (expired/wasted/spoiled) vaccine.

What Should Be Returned to McKesson?

- Spoiled or expired product in its original vial;
- Unused pre-filled syringes from manufacturers with an NDC printed on them; and
- Expired or compromised VFC vaccine must be reported to the Nevada State Immunization Program on Form 1: "Vaccine Request and Accountability Report" in column 4: "Doses Expired/Wasted".

Steps For Returning Expired/Spoiled Vaccines to McKesson:

- There are two methods of receiving mailing labels for expired/spoiled vaccines:
 - Receiving the label through email from McKesson; OR
 - Receiving the label through regular USPS mail

Receiving Return Labels Via Email:

- Complete the "VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine" (for the products eligible for return) and fax the completed form to the Nevada State Immunization Program at (775) 684-8338;
- Pack the non-viable VFC vaccines in any box for return to McKesson (do not add any private stock vaccines);
- Once the NSIP receives the pickup request, we will contact McKesson to send you mailing label(s) via email. The email will go to the person NSIP has on file as the Primary Vaccine Coordinator or contact for your clinic. There are specific guidelines you must follow when receiving the label(s):
 - The email address from which the label arrives from is uoltsupport@usp.com and in the subject line it will say "UPS Shipping API";
 - Once NSIP inputs the label request into the system, Tammy Brown will fax your request back to your clinic with verification that it was ordered. Once you receive the fax, the label will arrive in your email inbox approximately 30 – 60 minutes later. Check your spam email box if you don't see it in your inbox.
 - One label will arrive per email. If you have two boxes of vaccine to return, you will receive two separate emails with one label per email;
 - If you ordered two labels but only use one, you must put the unused shipping label in the box with the vaccine;
 - You cannot photo-copy or reprint the label to use at a later time on another shipment;

- After your office receives the mailing labels, contact a UPS driver for pickup; and
- Keep a copy of all vaccine return paperwork for up to three (3) years.

Receiving Return Labels Via USPS Mail:

- Complete the “VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine” (for the products eligible for return) and fax the completed form to the Nevada State Immunization Program at (775) 684-8338;
- Pack the non-viable VFC vaccines in any box for return to McKesson (do not add any private stock vaccines);
- Once the NSIP receives the pickup request, we will contact McKesson to send you mailing label(s) via normal mail (below is an example of the envelope for mailing labels that you will receive at your office);
- After your office receives the mailing labels, contact a UPS driver for pickup; and
- Keep a copy of all vaccine return paperwork for up to three (3) years.



Emergency Event Storage and Handling

The following procedures should be performed in the event of a power outage:

Short Term Power Outage:

- Record the time and temperature of the room, refrigerator and freezer using an unexpired, calibrated thermometer;
- If it is determined the power will only be out for a few hours, then tape the unit doors so no one can inadvertently open them and allow cold air to escape;
- When the power resumes, record the time and the temperatures in the refrigerator and freezer. If the temperatures are out of range, then do not use the vaccine; and
- Contact the NSIP Vaccine Manager and the vaccine manufacturers for instructions if VFC/state supplied vaccines are involved.

Long term Power Outage Due to a Natural or Manmade Disaster:

Facilities with a backup generator:

- Record the time and temperatures of the room, refrigerator and freezer using an unexpired, calibrated thermometer;
- Ensure the vaccine storage unit is plugged in an outlet that is supplied by the generator;
- Once the generator is supplying power to the storage unit, record the temperatures in the refrigerator and freezer again; and
- If the generator is not functioning, then prepare to transfer the vaccine to a functioning unit.

Facilities without a backup generator:

- Record the time and temperature of the room, refrigerator and freezer using an unexpired, calibrated thermometer;
- Gather cooler boxes, ice packs, bubble wrap and cardboard to pack the vaccines:
 - Place frozen ice packs in the bottom of the cooler boxes;
 - Place cardboard and then bubble wrap on top of the frozen ice packs;
 - Place the refrigerated vaccines on top of the bubble wrap;
 - Place an unexpired, calibrated thermometer in the middle with the vaccines;
 - Put another layer of bubble wrap and then cardboard on top of the vaccines; ○ Place another layer of frozen ice packs on top of the cardboard; and
 - Place the lid of the cooler box on the cooler and secure it with tape.
- **Frozen vaccines must be placed in a separate cooler box directly on frozen ice packs and surrounded by additional ice packs.**
- **Transport the vaccines to another location that has been coordinated with and not affected by the disaster in the CAB of a vehicle. NEVER transport vaccine in the trunk of a vehicle.**

Complete a Vaccine Incident Report and fax it to the NSIP as soon as possible at (775) 684-8338.

The following procedures should be performed in the event of a mechanical failure:

- Record the time and temperature of the room and the affected storage unit using an unexpired, calibrated thermometer; then
- Pack the vaccine in a bag and mark it "DO NOT USE";
- Place the vaccine in another freezer or refrigerator if the provider has more than one storage unit;
- Call each vaccine manufacturer and follow their directions to determine vaccine viability;
- Complete a Vaccine Incident Report immediately and fax it to the Nevada State Immunization Program. Ensure the report details if your vaccine is viable or spoiled; then
- Complete the "VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine" and fax to the NSIP at (775) 684-8338 to obtain a mailing label for return;
- Have the affected storage unit repaired or replaced;
- Complete 5 business days of temperature monitoring on the affected or new unit; then
- Fax the Temperature Log or Log Tag information to the Nevada State Immunization Program to obtain permission to return the vaccine to the affected unit; and
- Continue to monitor temperatures twice daily to ensure the repaired or new unit stays within the proper temperature ranges for continuous vaccine storage.

Request for Termination

An enrolled provider may request to become inactive at any time and must provide:

- Written notification on office letterhead which includes:
 - The date participation in the Nevada State Immunization Program will cease;
 - The reason for termination;
 - The ending inventory of the VFC/state supplied vaccines on hand including:
 - Lot Numbers,
 - Expiration Dates,
 - Number of doses remaining; and
 - A current Nevada State Immunization program Temperature Log or Log Tag download.

Upon receipt of this notification, the Nevada State Immunization Program will inactivate the provider as requested and the state or local health department will transfer any viable vaccines to another VFC-enrolled provider.

An inactive provider may request to be re-activated at any time; however, VFC/state supplied vaccines may not be requested by the re-activated provider until re-enrollment paperwork has been completed, a re-enrollment visit has been conducted, and the site is approved as being in compliance with current Nevada State Immunization Program Protocols.

Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. A copy of the VAERS report form can be found at <http://vaers.hhs.gov/esub/index>.

VAERS encourages the reporting of any significant adverse event that occurs after the administration of any vaccine licensed in the United States. Medical providers should report clinically significant adverse events, even if unsure whether a vaccine caused the event. **The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:**

- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine; and
- Any event listed in the Reportable Events Table that occurs within the specified time period after vaccination. A copy of the Reportable Events Table can be found at: <http://vaers.hhs.gov/resources/vaersmaterialspublications>.

Both the CDC and FDA review data reported to VAERS. The FDA reviews reports to assess whether a reported event is adequately reflected in product labeling and closely monitors reporting trends for individual vaccine lots. The CDC encourages all physicians to report any reaction following vaccination to VAERS, regardless of whether or not the physician believes that the vaccine caused the reaction. Reports sent to the VAERS Program that also make reference to non-vaccine pharmaceutical products are shared with MedWatch, the FDA's drug safety surveillance system.

To Obtain Additional Information About VAERS:

- Send e-mail inquiries to info@vaers.org;
- Visit the VAERS Website at <http://vaers.hhs.gov/index>;
- Call the toll-free VAERS information line at (800) 822-7967; or
- Fax inquiries to the toll-free information fax line at (877) 721-0366.

Safe Injection Practices

Safe Injection Practices:

The investigation of four large outbreaks of hepatitis B and hepatitis C virus among patients in ambulatory care facilities in the United States identified a need to define and reinforce safe injection practices. The four outbreaks occurred in a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The primary breaches in infection control practice that contributed to these outbreaks were 1) reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag) and 2) use of a single needle/syringe to administer intravenous medication to multiple patients. In one of these outbreaks, preparation of medications in the same workspace where used needle/syringes were dismantled also may have been a contributing factor. These and other outbreaks of viral hepatitis could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications. These include the use of a sterile, single-use, disposable needle and syringe for each injection given and prevention of contamination of injection equipment and medication.



Improper use of syringes, needles, and medication vials during routine healthcare procedures, such as administering injections have resulted in one or more of the following:

- Transmission of blood borne viruses, including hepatitis B and hepatitis C to patients;
- Notification of thousands of patients of possible exposure to blood borne pathogens and recommendation that they be tested for hepatitis B, hepatitis C, and HIV;
- Referral of providers to licensing boards for disciplinary action;
- Malpractice suits filed by patients.

These unfortunate events serve as a reminder of the serious consequences of failure to maintain strict adherence to safe injection practices during patient care. Injection safety and other basic infection control practices are central to patient safety. All healthcare providers are urged to carefully review their infection control practices and the practices of all staff under their supervision. In particular, providers should ensure that staff:

- Never administer medications from the same syringe to more than one patient, even if the needle is changed;
- Do not enter a vial with a used syringe or needle.

Hepatitis B, Hepatitis C, and HIV can be spread from patient to patient when these simple precautions are not followed. Additional protection is offered when medication vials can be dedicated to a single patient. It is important that:

- Medications packaged as single-use vials never be used for more than one patient;
- Medications packaged as multi-use vials be assigned to a single patient whenever possible;
- Bags or bottles of intravenous solution not be used as a common source of supply for more than one patient;
- Absolute adherence to proper infection control practices is maintained during the preparation and administration of injected medications.

Vaccine Administration

How to Administer Vaccines:

There are several resources available on how to administer vaccinations to persons of all ages. These include:

- Immunization Action Coalition
 - www.immunize.org/handouts/administering-vaccines.asp
- Pink Book
 - Appendix D
 - www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf
- EZ IZ Website
 - <http://eziz.org/eziz-training/>

Immunization Schedule:

The Nevada State Immunization Program requires all enrolled providers to follow the Advisory Committee on Immunization Practices (ACIP) recommended schedule. Alternative immunization schedules are not permitted unless for a specific medical circumstance.

The most current ACIP-released schedules can be found on the CDC website at: <http://www.cdc.gov/vaccines/schedules/index.html>

VFC Program Compliance Visits

All enrolled providers/clinics/facilities must be reviewed periodically as a condition of continued enrollment in the Nevada State Immunization Program:

Compliance site visits are performed to evaluate provider compliance with Vaccines for Children and Nevada State Immunization Program Protocols and address any noted deficiencies. Nevada State Immunization Program staff or its representatives will contact the providers/clinics for scheduling of the VFC compliance visit and review. If requested by the reviewer, the provider may need to respond to areas of non-compliance with a written corrective action plan. This corrective action plan is normally due within two weeks of the request; delays may result in temporary suspension of vaccine shipments.

Nevada State Immunization Program staff may conduct one or more of the following types of visits:

- **Nevada State Immunization Program Enrollment or Re-Enrollment Visit:** An enrollment visit includes education about the VFC and Nevada State Immunization Program guidelines, including proper vaccine storage and handling techniques. This visit is also an opportunity to establish a working relationship with the Nevada State Immunization Program representative. A re-enrollment visit will be made to providers/clinics that have: 1) requested to be reactivated in the program, 2) moved into a new facility, and/or 3) been delinquent in re-enrolling during the annual re-enrollment process.
- **VFC Compliance Visit:** A formal review of compliance with VFC standards for all VFC enrolled providers. The CDC's VFC Compliance Visit Questionnaire is completed and a review is conducted of a sampling of patient charts for documentation of VFC eligibility, including both VFC and non-VFC eligible children 18 years of age and younger. **The facility's Medical Director (the person who signed the VFC Agreement to Participate) must review the finding with the Quality Assurance Coordinator and sign the provided documentation.**
 - **VFC Follow-Up Visit:** An assurance check of issues of concern that arose from the VFC compliance visit. This follow-up visit may occur within one (1) to three (3) months of the original compliance visit. The facility's Medical Director or senior physician, who signed the enrollment forms, or a designee, is strongly recommended to attend.
- **AFIX Visit:** An assessment of the immunization rates of preschool and/or adolescent patients is completed utilizing data exported from Nevada WebIZ. A questionnaire will be completed either before or during the visit to identify areas of needed improvement. The provider will be asked to select 2 areas of quality improvement and implement activities to increase immunization rates.
 - **AFIX Follow-Up:** A follow-up to the AFIX visit to document that measures to improve immunization practices and delivery have been implemented. This follow-up visit normally occurs within six (6) months of the original visit. The facility's Medical Director or senior physician, who signed the enrollment forms, or a designee, is strongly recommended to attend. A second immunization assessment will be performed during this follow-up visit.
- **Educational Visit:** A visit that occurs when provider sites undergo significant staff turnover or to assist in an area for improvement, such as a review of the ACIP schedule, vaccine inventory reporting forms or developing written vaccine storage and handling plans.

- **Unannounced Storage And Handling Visit:** A visit that occurs when a site has had a vaccine wastage history of greater than 5% over all from doses ordered during the previous year. Vaccine storage procedures will be reviewed as well as historical temperature data.

Non-Compliance with Protocols

If an enrolled provider is found to be non-compliant with Vaccines for Children Program or Nevada State Immunization Program Protocols, then vaccine shipments to the provider may be suspended until a corrective action plan is submitted or other necessary steps are taken to correct deficiencies. **Failure to adequately correct serious deficiencies, such as those that jeopardize vaccine effectiveness, can result in removal of the provider from active participation in the program.**

The following actions may be taken and special provider status assigned:

Temporarily Inactive:

- Vaccine integrity cannot be assured because the temperature in the refrigerator was recorded as 32°F or 0°C, or lower at any given time without documented immediate corrective action; no thermometer in vaccine storage unit; no documentation of temperature checks of storage unit. When vaccine storage problems cause vaccine to be compromised, shipments may be suspended until the practice provides a one-week temperature log from the storage unit proving that it is capable of sustaining appropriate storage temperatures. Once reactivated, practices may need to provide weekly temperature logs to evaluators for up to two (2) months to ensure that vaccine storage problems have been resolved; or
- Refusal to cooperate with Nevada State Immunization Program requests for compliance visits, records, information or corrective action plans needed to meet program requirements.

Not Active (Inactive):

- The provider requests in writing to withdraw from the Nevada State Immunization Program;
- The provider is unwilling or has refused to comply with Nevada State Immunization Program Protocols; or
- The provider refuses to meet reasonable "standard of care" expectations by not adhering to the current ACIP Recommended Immunization Schedules.

Fraud & Abuse

The Nevada State Immunization Program Fraud & Abuse Policy provides guidance in the monitoring and prevention of fraud and/or abuse of VFC vaccines. This policy is consistent with standards established in the policy on fraud and abuse by the U.S. Centers for Disease Control and Prevention (CDC).

Background:

The Federal VFC Program was created as part of the Omnibus Budget Reconciliation Act, Section 1928 of the Social Security Act, in August 1993. The goal of this federally funded program is to improve vaccine availability nationwide by providing vaccines at no cost to VFC-eligible children through public and private providers enrolled in the program: <http://www.cdc.gov/vaccines/programs/vfc/index.html>. The VFC Program is operational in all 50 states and eight territories including the U.S. Virgin Islands, Puerto Rico and Guam.

Nevada began its VFC Program in 1994 as part of the President's Childhood Immunization Initiative. The VFC program is a Title XIX Medicaid program. Children who are VFC eligible are those who are under 19 years-old and: Medicaid-eligible, uninsured, underinsured and seen at a Federally Qualified or Rural Health Center, or are American Indian/Alaska Native. These children are entitled to receive low to no-cost pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices (ACIP). Nevada Check-Up (S-CHIP) is a non-Medicaid managed care program in Nevada. Effective October 1st 1998, children enrolled in Nevada Check-Up began receiving vaccines from the Nevada State Immunization Program that are distributed in the same manner as vaccines for VFC-eligible children (i.e., financed with Nevada State funds).

Purpose of the Fraud and Abuse Policy:

The purpose of the Nevada State Immunization Program's Fraud and Abuse Policy is to provide a standard operating procedure for prevention, detection, investigation and resolution of all suspected cases of provider fraud and/or abuse. All VFC providers are required to be enrolled and to re-enroll in the VFC program annually. The facilities medical director or equivalent must sign the *VFC Agreement to Participate* which specifies the VFC program requirements (available at http://health.nv.gov/Vaccine_VFCProgram.htm). Federal fraud and abuse laws apply to the entire VFC Program. In addition, providers who use Nevada Check-Up vaccines are also subject to the Nevada State Immunization Program's Fraud and Abuse Policy.

Suspected fraud and/or abuse will be identified by several mechanisms, which may include, but will not be limited to:

- Vaccine Request and Accountability Report;
- Eligibility Report of Doses Administered;
- VFC site or VFC education visits;
- Responses to high priority questions on the CDC VFC Site Visit Questionnaire;
- Verbal or written reports from provider staff;
- Verbal or written complaints from patients;
- Inconsistencies in reporting of vaccines in the immunization registry (Nevada WebIZ); and

- Any other information provided to the Nevada State Immunization Program that is deemed valid.

Reports of suspected fraud and/or abuse will be investigated immediately.

The Nevada State Immunization Program's Fraud and Abuse policy is to ensure that all VFC vaccines are administered only to VFC-eligible patients and that vaccine loss and wastage is minimized.

For the purposes of this Nevada State VFC Fraud & Abuse Policy, the following definitions will be used:

Fraud: Fraud is defined in the Code of Federal Regulations, Title 42, Part 455, Section 455.2 (42 CFR 455.2) as an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse: Abuse is defined in 42 CFR 455.2 as provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid Program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid Program.

Fraud and Abuse Policy Components:

All suspected cases of fraud and/or abuse will be reviewed by the following Immunization Program staff: Program Manager, Provider Quality Assurance Manager, Vaccine Manager, and other staff assigned to assist. Available data and complaints will be reviewed. If staff believes that fraud and/or abuse is suspected, then the case will be reported to the Centers for Medicare & Medicaid Services (CMS) - Medicaid Integrity Group with a copy to the CDC. CMS will then refer the suspected case to the Nevada Division of Health Care Financing and Policy (Nevada Medicaid) who will conduct the investigation following the Federal Regulatory scheme at 42 CFR sections 455.15.

The Nevada State Immunization Program will track all suspected cases of fraud and/or abuse in a database to monitor and document all actions taken on allegations related to fraud and/or abuse, including actions taken to address identified situations.

The Immunization Program Manager will serve as the primary person to: a) make the referral, and b) notify appropriate governmental agencies. The Vaccine Manager and Provider Quality Assurance Manager will serve as the first and second back-up referral positions.

Examples of Fraud & Abuse:

1. Examples of actions that might constitute potential fraud and/or abuse:
 - Providing VFC vaccine to non VFC-eligible children. If the provider administers immunizations to fully insured children, then that vaccine must be privately purchased;
 - Selling or otherwise misdirecting VFC vaccine;
 - Billing a patient or third party for VFC vaccine;

- Charging more than the established maximum regional charge for administration of a VFC vaccine to a VFC-eligible child;
 - Denying VFC-eligible children VFC vaccine because of parent/legal guardians' inability to pay the administration fee;
 - Abusing Delegation of Authority privilege - this includes allowing fully insured patients to be categorized as "underinsured;"
 - Failing to implement the provider enrollment requirements of the VFC program;
 - Failing to screen patients for VFC eligibility at every immunization visit;
 - Failing to maintain VFC records and comply with other requirements of the VFC program;
 - Failing to fully account for VFC vaccine;
 - Failing to properly store and handle VFC vaccine;
 - Ordering VFC vaccine in quantities or patterns that do not match the provider's profile or otherwise involve over-ordering of VFC vaccine; and
 - Wasting of VFC vaccine due to negligence or non-compliance.
2. All cases of intentional fraud and/or abuse situations will be examined by the Nevada State Immunization Program and referred to the Centers for Medicare and Medicaid Service (CMS), Medicaid Integrity Group (MIG).

Wasted Vaccine Definitions:

Wasted vaccine is listed above under *Examples of Fraud and Abuse*. **Any vaccine that cannot be used is considered "wasted," including expired vaccine, spoiled vaccine, or vaccine which is unaccounted for.** Wasted vaccine that is determined by the Nevada State Immunization Program to have been wasted due to negligence or non-compliance on the part of the provider may be subject to dose-for-dose replacement.

1. **Expired:** Vaccine that is past the expiration date.
2. **Spoiled:** Any vaccine that exceeds the limits of approved cold chain procedures or is pre-drawn and not used within acceptable time frames (an opened multi-dose vial is not spoiled until the expiration date has passed), or vaccine that has been delivered in non-viable condition
3. **Unaccounted For:** Any vaccine that has been lost in transit by the distributor or manufacturer, or vaccine not accounted for by monthly usage and inventory reports. This can be reflected by usage data or inventory discrepancies that reflect unaccounted for vaccine.

Wasted Vaccine Scenarios:

This list includes but is not limited to the following scenarios:

1. Non-Preventable Vaccine Loss

- a. The carrier (UPS, FedEx etc ...) does not deliver in a timely manner. Before making the determination that the vaccine is non-viable, the provider must first contact the Nevada State Immunization Program and vaccine manufacturers;
- b. An alert/alarm company does not notify the provider of a refrigerator or freezer malfunction;
- c. Power is interrupted or discontinued due to a [storm, earthquake] natural or man-made disaster;

- d. Vaccine is moved to a nearby facility due to anticipated inclement weather, the facility experiences a power failure, and the vaccine is later deemed to be non-viable;
- e. A vial that is accidentally dropped or broken;
- f. Vaccine that is drawn at the time of visit, but not administered due to parental refusal or a change in physician orders; and/or
- g. Extraordinary situations not listed above which the Nevada State Immunization Program deems to be beyond the provider's control.

2. Preventable Vaccine Loss

Loss Due To Negligence: Below is a list of situations that may be considered "provider negligence" and will require vaccine purchased with state (S-CHIP) or federal funds (VFC, 317) to be replaced by the provider on a dose-for-dose basis. Situations that occur which are not listed here will be considered on a case-by-case basis by the Nevada State Immunization Program.

- a. Failure to establish and/or annual review an "Office Vaccine Management Plan";
- b. Failure to rotate or transfer vaccine that results in expired vaccine, and the Nevada State Immunization Program was not notified at least three months before the vaccine's expiration date;
- c. Pre-drawing vaccine before screening patients;
- d. Leaving vaccine out of the refrigerator/freezer so it becomes non-viable;
- e. Vaccine stored improperly (example - refrigerating vaccine that should have been frozen, freezing vaccine that should have been refrigerated, or storing any vaccine in a dormitory-style refrigerator, even for day use);
- f. Leaving a refrigerator or freezer unplugged or an electrical breaker switched off. (A "Do Not Unplug" sticker should be on the front of each vaccine refrigerator/freezer AND an "Expensive Vaccine in Storage" sticker is required at each outlet and circuit breaker);
- g. Leaving a refrigerator or freezer door open or ajar, whether by staff, contractors, or guests;
- h. Improper maintenance of recommended refrigerator and freezer temperatures resulting in vaccine spoilage, including prolonged storage of vaccines when out of range temperatures are recorded. **(Note: Temperatures recorded on temperature logs will be considered official in making vaccine viability decisions. Also, a thermometer's margin of error will not be considered when temperatures are recorded at or below 35°F/2°C or above 46°F/8°C.);**
- i. Failing to act according to your facility's office vaccine management plan in a power outage;
- j. Transporting/shipping vaccine in a manner that does not maintain the cold chain appropriately at all times;
- k. Failure to notify the Nevada State Immunization Program when provider office hours change or the practice moves, resulting in vaccines being undeliverable and consequently spoiled;
- l. Failure to maintain alarm devices properly;
- m. Relying solely on electronic temperature monitoring and not manually checking and documenting temperatures twice daily;
- n. Failure to be available to receive and properly store vaccine shipments per the established office hours;
- o. Failure to use approved vaccine storage units. Dorm-style units are NOT acceptable. Approved vaccine storage units can be found on our website: http://health.nv.gov/Vaccine_VFCProgram.htm; and/or

- p. Failure to use digital, unexpired calibrated thermometers that are certified by a laboratory accredited by an ILAC MRA signatory body or by an entity that provides documentation demonstrating testing that meets ISO/IEC 17025 international standards.

Loss Due to Non-Compliance: VFC vaccine not accounted for by monthly usage and inventory reports. This can be reflected by usage data or inventory discrepancies that reflect lost vaccine supply. Examples include:

- a. Failure to document vaccine usage or inaccuracy in reporting vaccine usage or inventory received on:
 - I. Vaccine Request and Accountability form;
 - II. Vaccine Lot Number Inventory Report form; or
 - III. Eligibility Report of Doses Administered form.
- b. Knowingly administering VFC vaccine to children not eligible for the VFC program, includes the following:
 - I. Administering VFC vaccine to patients who are over 18 years of age;
 - II. Administering VFC vaccine to every patient in the practice whether eligible or not (example - a provider discontinues purchasing private stocks of vaccine for administration to fully, privately insured patients);
 - III. Administering VFC vaccine because the reimbursement rate of the child's insurance company is low;
 - IV. Administering VFC vaccine to a child who is fully insured, including administration of VFC vaccine to a child who has not met their deductible in order to save the parent the cost of the deductible (high deductible plan still means a child is fully insured and therefore not VFC eligible); and/or
 - V. Administering VFC vaccine to a child even though the insurance company provides a flat rate of coverage for immunizations for the year (upon exhaustion of flat rate coverage, the child is then eligible for VFC vaccine).
- c. Accepting reimbursement from insurance companies or patients for VFC vaccine as evidenced by:
 - I. Administering VFC vaccine to a child and subsequently billing the child's insurance for the cost of the vaccine;
 - II. Charging the patient for the cost of the vaccine; or
 - III. Charging a Medicaid recipient any fee at all.

Non-Preventable Loss: No action will be taken for recapture if the Nevada State Immunization Program determines the vaccine loss was not due to negligence or non-compliance on the part of the provider.

Loss Due to Negligence: Action may be taken by the Nevada State Immunization Program to recapture vaccine loss on a dose-for-dose basis if it is determined the loss was due to negligence on the part of the provider. The provider must submit receipt of purchase to NISP within 90 days (or less) demonstrating that all doses were replaced appropriately.

Loss Due to Non-Compliance: Action may be taken by the Nevada State Immunization Program to recapture vaccine loss on a dose-for-dose basis if it is determined the loss was due to non-compliance on the part of the provider. The provider must submit receipt of purchase to NSIP within 90 days demonstrating that all doses were replaced appropriately.

Providers are encouraged to have insurance policies in place to cover the cost of wasted vaccine that was privately purchased.

Course of Action for Financial Recapture of Wasted Vaccine:

The Nevada State Immunization Program allows for up to a 5% vaccine wastage loss on an annual basis. This means that if a provider received 100 doses annually, up to 5 doses may be allowable in wastage, with no consequences. Anything above this threshold may be due to negligence or non-compliance and therefore the provider may be subject to replace the vaccine on a dose-for-dose basis.

Who Will Investigate?

The Nevada State Immunization Program is not responsible for the official investigation of fraud and/or abuse of the VFC Program. Instead, when the Nevada State Immunization Program identifies suspicious activity via data or written or verbal reports the program will only review the case. If the Nevada State Immunization Program determines that further investigation is warranted or justified, then the case will be reported to the CMS - Medicaid Integrity Group with a copy to the CDC. The VFC Program, as a component of each state's medical assistance plan, is considered a Title XIX Medicaid Program. All suspected cases of VFC fraud and abuse are referred to the CMS Medicaid Integrity Group for further referral – usually the state Medicaid agency (Nevada Division of Health Care Financing and Policy), which will then formally investigate the case.

Criteria that will be considered during a fraud and/or abuse investigation include:

- Past VFC Program compliance by the provider up to the time of the incident;
- Proper vaccine storage compliance by the provider;
- How the incident was reported/identified;
- Length of time the situation was occurring;
- Inadvertent financial gain of the provider;
- The amount of money lost by the Nevada State Immunization Program;
- The provider's willingness to replace dose for dose the lost VFC vaccine with privately purchased vaccine; and
- The provider's willingness to participate in the education visit referral and post-education follow-up.

If an instance of fraud and/or abuse is determined to result from an excusable lack of knowledge or understanding of the Nevada State Immunization Program, then secondary education and a corrective action plan will be implemented. If an instance of fraud and/or abuse is determined to be intentional and the provider has received financial benefits from the behavior, then the situation will require immediate referral to CMS - Medicaid Integrity Group with a copy to the CDC. The provider will be temporarily suspended by the Nevada State Immunization Program pending the outcome of a more in-depth investigation.

If a VFC-enrolled provider is not compliant with VFC Program Protocols or fraud and/or abuse is suspected or reported, then vaccine shipments to the provider may be suspended until a corrective action plan is submitted or other necessary steps are taken to correct deficiencies. Corrective actions may include more frequent compliance visits and monitoring of records or replacement of vaccine damaged through provider negligence at the provider's expense. Failure to adequately correct serious deficiencies may result in enrolling the provider into a formal education process, termination of provider participation in the VFC Program or in the case of suspected fraud, referral for criminal prosecution or civil resolution.

Detection and Monitoring of Fraud and Abuse:

All provider compliance visits will include completion of Section I of CDC's VFC Compliance Visit Questionnaire. All compliance visit reports submitted by field staff, including all documented cases of potential fraud and/or abuse, and all compliance visit findings and recommendations will be reviewed by the Provider Quality Assurance Manager and, if appropriate, by the Vaccine Manager, and then referred to the Nevada State Immunization Program Manager for final action.

Failure to Comply with Nevada State Immunization Program VFC Requirements:

On an annual basis, all VFC providers must re-enroll in the VFC Program. This includes completing the most current VFC Agreement to Participate. This application includes all mandatory components of the VFC Program with which providers must comply.

Consequences:

Any provider found guilty of fraud and/or abuse will be subject to:

- Replacement of VFC vaccines on a dose-for-dose basis;
- Termination from the VFC Program;
- Loss of Delegation of Authority; and
- Other consequences deemed appropriate by the Nevada Division of Health Care Financing and Policy.

Appeals Process:

For decisions and findings rendered by the Nevada State Immunization Program a provider must follow guidance for the appeals process.

Per Nevada Revised Statutes (NRS) 439.200, 233B.130, and corresponding regulation in Nevada Administrative Code (NAC) 439.300 – 439.395, providers have the right to appeal decisions made by the Nevada State Immunization Program in regards to termination from the VFC Program or financial responsibility to replace vaccines.

If the Nevada State Immunization Program has made the decision to invoice a provider for loss of vaccine or terminate a provider from the VFC Program, then the provider will receive a notice of disciplinary action from the program. If the provider wishes to appeal the notice, then the provider has 10 days to submit an appeal to dispute the notice. If an appeal is not received within 10 days of notice, then the decision is considered final.

If an appeal is received within 10 days of the notice, then the Nevada State Division of Public and Behavioral Health Administrator will assign a hearing officer for a formal proceeding. A formal hearing will be set and a decision will be made by the hearing officer based on evidence provided by both the Nevada State Immunization Program and the provider. All decisions made by the hearing officer are final unless either party wishes to seek judicial review in a court of law.